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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,986	01/11/2002	Tim E. Ward	265/282	1411

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EXAMINER

IMAM, ALI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 02/25/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,986

Applicant(s)

WARD ET AL. *en*

Examiner

Ali Imam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. In response to the amendment filed 11/28/2003, all necessary changes to the claims have been entered.

Response to Arguments

2. Applicant's arguments filed 11/28/03 have been fully considered but they are not persuasive. Applicant's core argument is that Davis or Terwillinger in view of Davis fails to disclose the plural slots having a curved upper surface and substantially flat bottom surface. The examiner respectfully disagrees. Davis teaches in Fig. 2 and Terwillinger teaches in Fig. 4, the slots having a curved upper surface and substantially flat bottom surface.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

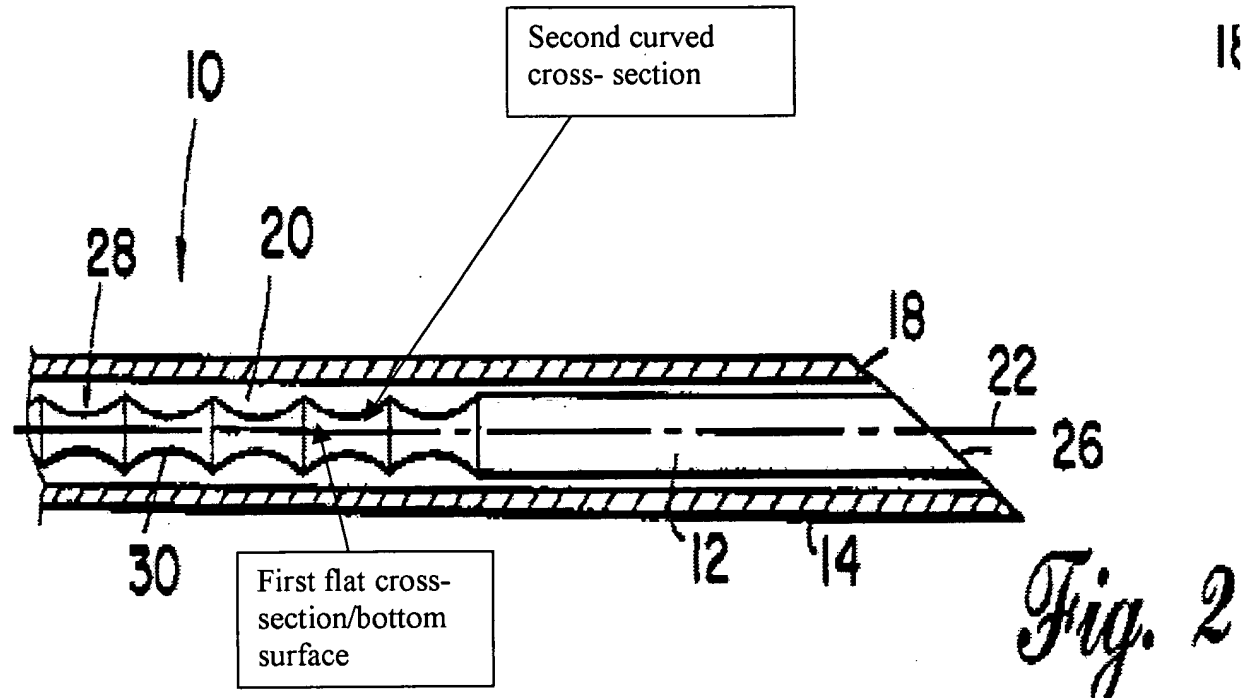
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (US 5,820,554).

In regard to claims 1, 12, 16, 19, 33, 29, 34, and 39, Davis teaches in Figs. 1-4, a medical device/catheter/needle (10) comprising an elongated body (12); a plurality of concave slot/grooves (28) formed on the distal end (26) of the body (12); wherein a first surface of each concave slots is substantially flat in one cross section or has a bottom surface that follows the contours of the contoured surface and wherein a second surface of each concave slots is

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substantially curved and wherein the first curved section/bottom surface is perpendicular to the second cross section (please see reproduced Fig. 2 below).



In regard to claims 8, 25, and 38, Davis teaches a needle (10).

In regard to claims 2-5, 9-11, 13-15, and 35, Davis teaches in Figs. 2-4 the various arrangements of the first and second surfaces of the plural slots such as perpendicular or radial.

In regard to claims 6, 23, and 36, Davis teaches that the surface is made of stainless steel (col. 3, line 58).

In regard to claims 7, 24, and 37, Davis teaches that the surface can be alternatively made of plastic materials (col. 5, line 38).

In regard to claims 17, 18, 20-22, 26-28, and 30-32, Davis teaches in Figs 2-4, that the curved surface can be convex or concave.

In regard to claim 40, Davis's outer surface of the needle is configured to be directly inserted into the body.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwilliger (US 5,766,135 of record) in view of Davis et al. (US 5,820,554).

In regard to claims 1, 19, and 34, Terwilliger teaches in Fig. 4, a medical device (10) comprising an elongated body (12); a concave hole/slot (2) formed on the distal end of the body (12); wherein a surface (3) of the slot is also concave (col. 4, line 5). Terwilliger further teaches that the medical device is a needle (col. 2, line 55)

Terwilliger fails to mention specifically that the body includes plurality of concave slots instead of just one slot (2). Terwilliger further fails to mention expressly that the surface (3) is substantially flat in a first cross section and is substantially curved in a second cross section.

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Davis teaches in col. 4, lines 25-39 and col. 6, lines 30-33, an ultrasound biopsy needle system comprising plural slots having first surface being substantially flat and the second surface being substantially curved. Davis further teaches that plural slots having the disclosed shapes enhances echogenicity of the ultrasound probe.

Therefore, it would have obvious to an ordinary skill in the art, at the time the invention was made, to modify Terwilliger's medical device such that it's body (12) includes plural slots and the surface (3) of each plural slots is substantially flat in a first cross section and is substantially curved in a second cross section in order to increase echogenicity of the medical imaging device for providing enhanced ultrasonic visibility.

In regard to the specific limitations of claims 2-18, 20-33, and 35-39 regarding the shapes, materials, and structures of the concave slot and the elongated body are considered to be a matter of users' discretion in order to achieve intended echogenecity for the medical device for increasing ultrasonic visibility of the medical device.

In regard to claim 40, Terwilliger's outer surface of the needle is configured to be directly inserted into the body.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Imam whose telephone number is 703-305-0028. The examiner can normally be reached on Mon. - Th., 8:00- 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703-308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ali Imam
Primary Examiner
Art Unit 3737

AMI
2/23/2004